DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: Mylan Pharmaceuticals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been

redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR pt. 0, subpt. R, App.

In accordance with 21 CFR 1301.34(a), this is notice that on October 6, 2014, Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, applied to be registered as an importer of the following basic classes of controlled substances:

Controlled Substance	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Methadone (9250)	II
Morphine (9300)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Dated: January 9, 2015.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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